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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,306	10/23/2001	Brian R. Dixon	5048P1C1D1	8710
35969	7590	04/01/2004	EXAMINER	
JEFFREY M. GREENMAN BAYER PHARMACEUTICALS CORPORATION 400 MORGAN LANE WEST HAVEN, CT 06516			MCKENZIE, THOMAS C	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 04/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)
	10/004,306	DIXON ET AL.
	Examiner	Art Unit
	Thomas McKenzie, Ph.D.	1624

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 15 March 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) The period for reply expires 6 months from the mailing date of the final rejection.
- b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

- 1. A Notice of Appeal was filed on 15 March 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
- 2. The proposed amendment(s) will not be entered because:
 - (a) they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) they raise the issue of new matter (see Note below);
 - (c) they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

- 3. Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
- 4. Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
- 5. The a) affidavit, b) exhibit, or c) request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
- 6. The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
- 7. For purposes of Appeal, the proposed amendment(s) a) will not be entered or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: 8 and 9.

Claim(s) objected to: 6.

Claim(s) rejected: 1-3 and 7.

Claim(s) withdrawn from consideration: _____.

- 8. The drawing correction filed on _____ is a) approved or b) disapproved by the Examiner.
- 9. Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.
- 10. Other: _____

Continuation of 3. Applicant's reply has overcome the following rejection(s):

Applicants' correction of a typo in claim 1 overcomes the claim objection made in point #3 of the Final rejection. Applicants' addition to proviso g) of claim 1 overcomes the art rejection over Ishimitsu (JP 63-41471 A2) made in point #5. However, those additions also raise the new matter rejections discussed in point #4 of that action.

Continuation of 5. does NOT place the application in condition for allowance because: Applicants cite two cases in support of their position concerning the Grasselli rejection. The Examiner wants to make clear there are two grounds for the present rejection, the Grasselli decision concerning new negative limitations and the lack of blazemarks in the specification pointing to the chemical names Applicants are now excluding. Applicants cite both *In re Johnson* 194 USPQ 187 as legal precedent for newly introduced negative provisos and Applicants rely upon the earlier decision of *In re Wertheim, et al.*, 191 USPQ 90 for the proposition that Applicant are allowed to "claim as patentable to them is less than what they describe as their invention" (at 97).

In re Johnson 194 USPQ 187 may be factually and legally distinguished from the present situation. The U.S. Court of Customs and Patent Appeals made clear that the context in which the amendments were made were important to their

decision. The issue decided *In re Johnson* 194 USPQ 187 arose from an interference situation. The art from which Johnson was attempting to distance himself was in a competing application and could not have been known to Johnson at the time of his filing. In the present Application and in *Ex parte Grasselli, et al.* 231 USPQ 393, the negative limitations were introduced to avoid art published before Appellant's filing date.

The legal issue decided *In re Johnson* 194 USPQ 187 was that of an interference situation as affected by the 35 USC 112 first paragraph issue, which is not at issue here. The court held "it is not true that the factual context out of which the question under §112 arises is immaterial". The decision in *Ex parte Grasselli, et al.* 231 USPQ 393, was rendered six years after *In re Johnson* 194 USPQ 187, relied upon by the Appellant. In *Ex parte Grasselli, et al.*, 231 USPQ 393 the editor of the USPQ noted that, "[t]his decision was affirmed by the U.S. Court of Appeals for the Federal Circuit in an unpublished memorandum opinion, 738 F.2d 453 (1984)". Thus, it is unclear why Appellants believe the decision *In re Johnson* 194 USPQ 187 supercedes that of *Ex parte Grasselli, et al.* 231 USPQ 393.

In re Wertheim, et al., 191 USPQ 90 concerned the freeze-drying of coffee and whether the limitations "at least 35%" and "between 35% and 60%" had support in a priority document teaching "25% to 60%. Numerical ranges in a process

limitation are treated differently than chemical compounds from a Markush formula. The U.S. Court of Customs and Patent Appeals held In re Wertheim, et al., 191 USPQ 90, "[w]e see an important practical distinction between broad generic chemical compound inventions, for example, as In re Ruschig, *supra*, in which each compound within the genus is a separate embodiment of the invention, and inventions like that at bar, in which the range of solids content is but one of several process parameters." Thus, while Applicant are entitled to claim less than they originally intended, in response to art, the procedure for doing so must take into account the special features of a chemical formula. Applicant may not simply exclude, by name, individual compounds.

In any event, the names and formulas of these possible 92 elements making up Grasselli's catalyst are easily found in the periodic chart hanging on every chemist's wall. What are not so easy to find are names of the eleven compounds Applicant are now excluding by proviso. Appellant's provisos exclude eleven specific compounds by name. Nowhere in the application as filed are these specific compounds named. These eleven compounds, as such, were unknown to Appellant until cited by the Examiner as prior art. It is a settled principal of patent law that disclosure of a class of compounds using only a generic formula does not

permit Appellant to claim any particular compound within that class, *In re Shokal et al.*, 113 USPQ 283,

"this court has repeatedly held that the disclosure of a broad range of compounds does not necessarily confer a right to claim each individual compound or group within that range. Arness v. Franks, 31 C.C.P.A. (Patents) 737, 138 F.2d 213, 59 USPQ 154; In re Rodman et al., 42 C.C.P.A. (Patents) 951, 223 F.2d 281, 106 USPQ 142; Prutton v. Fuller et al., 43 C.C.P.A. (Patents) 831, 230 F.2d 459, 109 USPQ 59".

In re Ruschig, Aumuller, Korger, Wagner, Scholz, and Bander, 154 USPQ 118,

"is not our view that a disclosure such as that to be found in the formula and words of claim 2, above, amounts to a disclosure, sufficient to support a specific claim, of every compound a skilled chemist can see is within the scope of that claim. Specific claims to single compounds require reasonably specific supporting disclosure and while we agree with the appellants, as the board did, that naming is not essential, something more than the disclosure of a class of 1000, or 100, or even 48, compounds is required. Surely, given time, a chemist could name (especially with the aid of a computer) all of the half million compounds within the scope of the broadest claim, which claim is supported by the broad disclosure. This does not constitute support for each compound individually when separately claimed."

Fujikawa v. Wattanasin 39 USPQ2d 1895,

"the Board again recognized that the compounds of the proposed count were not Wattanasin's preferred, and that his application contained no blazemarks as to what compounds, other than those disclosed as preferred, might be of special interest. In the absence of such blazemarks, simply describing a large genus of compounds is not sufficient to satisfy the written description requirement as to particular species or sub-genuses."

It follows logically that since the eleven species newly excluded by proviso are now of special interest to Applicant, even a negative limitation must require blaze marks pointing directly to those eleven compounds.

The U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences in *Ex parte Winters* 11 USPQ2d 1387, held that a small subgenus of 4 compounds requires description. "But the original disclosure does not describe any of those species either by way of working example or otherwise. There is no support for any of those species per se. Nor are there guidelines in the original disclosure which would lead a person having ordinary skill in the art toward the subgenus of compounds defined in claim 42. On the contrary, the written description in appellant's specification tends to lead away from the subgenus."

Note also the holding in *Fujikawa v. Wattanasin* 39 USPQ2d 1895, "that his application contained no blazemarks as to what compounds, other than those disclosed as preferred, might be of special interest. In the absence of such blazemarks, simply describing a large genus of compounds is not sufficient to satisfy the written description requirement as to particular species or sub-genuses."

In the present case, the subgenus is the formula of claim 1 after the eleven named species are carved out.

TCMcK/me 

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